

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF TENNESSEE  
NORTHEASTERN DIVISION**

MARJORIE HELEN LEWIS and	)	
Husband, RONALD LEWIS	)	
	)	
Plaintiffs,	)	CIVIL ACTION NO. 2:12cv00115
v.	)	
	)	
NEW ENGLAND COMPOUNDING	)	
PHARMACY, INC., d/b/a NEW	)	
ENGLAND COMPOUNDING CENTER,	)	
AMERIDOSE, LLC, MEDICAL SALES	)	
MANAGEMENT, INC., BARRY J.	)	
CADDEN, GREGORY A.	)	
CONIGLIARO, DOUGLAS A.	)	
CONIGLIARO, LISA CONIGLIARO	)	
CADDEN, CARLA R. CONIGLIARO, and	)	
GLENN A. CHIN	)	
	)	
Defendants	)	

**ANSWER OF DEFENDANT MEDICAL SALES MANAGEMENT, INC.**

Defendant, Medical Sales Management, Inc. ("Defendant"), by and through its undersigned counsel, hereby answers Plaintiffs' Complaint as follows:

1. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1.
2. Defendant admits that, at all relevant times, New England Compounding Pharmacy, Inc. did business as New England Compounding Center ("NECC"). Defendant also admits that NECC is a Massachusetts corporation with its principal place of business located at 697 Waverly Street, Framingham, Massachusetts. Defendant further admits that, at or about the time this action was commenced, the registered agent for service of process for NECC was

Gregory A. Conigliaro. Defendant is not required to respond to the remaining allegations in Paragraph 2 that set forth legal conclusions.

3. Defendant denies that Ameridose, LLC (“Ameridose”) is a corporation, but admits that it is a Massachusetts domestic Limited Liability Company with its principal place of business located at 205 Flanders Road, Westborough, Massachusetts. Defendant further admits that, at or about the time this action was commenced, the registered agent for service of process for Ameridose was Gregory A. Conigliaro. Defendant is not required to respond to the remaining allegations in Paragraph 3 that set forth legal conclusions.

4. Defendant admits that it is a Massachusetts corporation with its principal office at 697-701 Waverly Street. Defendant denies that its principal office is located in Framington, Massachusetts, but admits that it is located in Framingham, Massachusetts. Defendant further admits that, at or about the time this action was commenced, the registered agent for service of process for Defendant was Gregory A. Conigliaro. Defendant is not required to respond to the remaining allegations in Paragraph 4 that set forth legal conclusions.

5. Defendant admits that, at or about the time this action was commenced, Barry J. Cadden was a resident of Massachusetts and a part owner, officer and director of NECC. Defendant further admits that, at or about the time this action was commenced, Barry J. Cadden was a part owner of Ameridose. Defendant denies that, at or about the time this action was commenced, Barry Cadden was a manager of Ameridose, LLC. Defendant is not required to respond to the remaining allegations in Paragraph 5 that set forth legal conclusions.

6. Defendant admits that, at or about the time this action was commenced, Gregory A. Conigliaro was a resident of Massachusetts, as well as a part owner, officer and director of NECC. Defendant further admits that, at or about the time this action was commenced, Gregory

A. Conigliaro was a part owner and manager of Ameridose, LLC. Defendant is not required to respond to the remaining allegations in Paragraph 6 that set forth legal conclusions.

7. Defendant admits that, at or about the time this action was commenced, Douglas A. Conigliaro was a resident of Massachusetts, as well as a part owner, president and director of Defendant. Defendant is not required to respond to the remaining allegations in Paragraph 7 that set forth legal conclusions.

8. Defendant admits that, at or about the time this action was commenced, Lisa Conigliaro Cadden was a resident of Massachusetts and a part owner and director of NECC. Defendant further admits that, at or about the time this action was commenced, Lisa Conigliaro Cadden was a part owner of Ameridose, but denies that she was a director of Ameridose. Defendant is not required to respond to the allegations in Paragraph 8 that set forth legal conclusions. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 8.

9. Defendant admits that, at or about the time this action was commenced, Carla Conigliaro was a resident of Massachusetts and a part owner and director of NECC. Defendant further admits that, at or about the time this action was commenced, Carla Conigliaro was a part owner of Ameridose, but denies that she was a director of Ameridose. Defendant is not required to respond to the remaining allegations in Paragraph 9 that set forth legal conclusions.

10. Defendant admits that, at or about the time this action was commenced, Glen A. Chin was a resident of Massachusetts. Defendant is not required to respond to the remaining allegations in Paragraph 10 that set forth legal conclusions.

11. Defendant is not required to respond to the allegations of Paragraph 11 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

12. Defendant is not required to respond to the allegations of Paragraph 12 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

### **RESPONDING TO FACTUAL ALLEGATIONS**

13. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 13 as to Plaintiff Marjorie Helen Lewis's medical condition and treatment. Defendant is not required to respond to the allegations of Paragraph 13 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

14. Defendant is not required to respond to the allegations of Paragraph 14 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

15. The statements of the U.S. Food and Drug Administration speak for themselves. Defendant is not required to respond to the allegations in Paragraph 15 that set forth legal conclusions.

16. Defendant is not required to respond to the allegations of Paragraph 16 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

17. Defendant is not required to respond to the allegations of Paragraph 17 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

18. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 18 as to Plaintiff Marjorie Helen Lewis's treatment. Defendant is not required to respond to the allegations of Paragraph 18 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

19. Defendant is not required to respond to the allegations of Paragraph 19 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

20. The statements of the Center for Disease Control, U.S. Food and Drug Administration, and the Commonwealth of Massachusetts Office of Health and Human Services speak for themselves. Defendant lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 20.

21. Defendant is not required to respond to the allegations of Paragraph 21 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

#### **RESPONDING TO ALLEGED WRONGS**

22. Defendant is not required to respond to the allegations of Paragraph 22 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

23. Defendant admits that, at or about the time this action was commenced, Barry J. Cadden, Gregory A. Conigliaro and Douglas A. Conigliaro were part owners, officers, and directors of Defendant. Defendant further admits that, at or about the time this action was commenced, Lisa Conigliaro Cadden and Carla R. Conigliaro were part owners of Defendant. Defendant is not required to respond to the allegations of Paragraph 23 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

24. Defendant is not required to respond to the allegations of Paragraph 24 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

25. Defendant is not required to respond to the allegations of Paragraph 25 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

26. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26 as to Plaintiff's medical treatment. Defendant is not required to respond to the allegations of Paragraph 26 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

27. Defendant is not required to respond to the allegations of Paragraph 27 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

28. Defendant is not required to respond to the allegations of Paragraph 28 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- a. Defendant is not required to respond to the allegations of Paragraph 28(a) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- b. Defendant is not required to respond to the allegations of Paragraph 28(b) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- c. Defendant is not required to respond to the allegations of Paragraph 28(c) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- d. Defendant is not required to respond to the allegations of Paragraph 28(d) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- e. Defendant is not required to respond to the allegations of Paragraph 28(e) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- f. Defendant is not required to respond to the allegations of Paragraph 28(f) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
- g. Defendant is not required to respond to the allegations of Paragraph 28(g) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

- h. Defendant is not required to respond to the allegations of Paragraph 28(h) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
  - i. Defendant is not required to respond to the allegations of Paragraph 28(i) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
  - j. Defendant is not required to respond to the allegations of Paragraph 28(j) that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.
29. Defendant is not required to respond to the allegations of Paragraph 29 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

#### **RESPONDING TO ALLEGED INJURIES AND DAMAGES**

30. Defendant lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 30 as to Plaintiffs' alleged injuries and damages. Defendant is not required to respond to the allegations of Paragraph 30 that set forth legal conclusions. However, to the extent such allegations may be construed against Defendant, they are denied.

#### **RESPONDING TO WHEREFORE CLAUSE**

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.



## **DEFENSES AND AFFIRMATIVE DEFENSES**

During the course of litigation, a number of defenses and/or affirmative defenses may become available to Defendant. To the extent any of the following is available and may apply, notice hereby is given of the following:

1. The Complaint fails to state a claim or cause of action cognizable in law or equity.
2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy.
3. The Complaint may be barred, in whole or in part, by applicable statutes of limitation and/or repose.
4. Standing to sue may be lacking on all or some of the claims.
5. This action may be dismissed and/or transferred under the doctrine of forum non conveniens.
6. No injury has been sufficiently stated or proven.
7. The Complaint fails to sufficiently identify a preparation compounded or dispensed by the Defendant.
8. The alleged injuries or damages may not have been proximately caused by the Defendant.
9. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of the Defendant.
10. The injuries or damages alleged may have been caused or contributed to by pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases, or illnesses.

11. The injuries or damages alleged may have been caused or contributed to by an idiosyncratic reaction to any compounded or dispensed preparation.

12. The alleged injuries or damages may have been caused or contributed to by known risks inherent in certain medical procedures, and which are otherwise open and obvious, or that were voluntarily undertaken, with full knowledge and consent. Such risks were therefore assumed and accepted through consenting and engaging in said medical procedures.

13. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

14. The preparations compounded and dispensed were intended to be used and administered only by licensed health care practitioners in the care and treatment of their patients. Such licensed health care practitioners were knowledgeable, learned intermediaries and sophisticated users in treating patients and performing medical procedures.

15. The alleged injuries or damages may have been caused by the unforeseeable misuse, abuse, or inappropriate handling of the preparation by others, which was unforeseeable to the Defendant.

16. The preparation may have been modified, altered or changed from the condition in which it was originally compounded and dispensed, which modification, alteration, or change caused or contributed to the alleged injuries or damages.

17. Claims under applicable state law fail to state any claim upon which relief can be granted.

18. To the extent that comments (g), (h), (i), (j) and (k) of Section 402A of the Restatement (Second) of Torts and Comment (b) of Section 6 of the Restatement (Third) of Torts are applicable, such provisions may be relied on in defense of this action.

19. Damages, if any, have not been appropriately mitigated.
20. The injuries or damages alleged may have been caused in whole or in part by the purported contributory negligence and/or culpable conduct of others and not as a result of any conduct on the part of the Defendant. Recovery, if any, should be limited or reduced in proportion to the parties' purported comparative fault and in accordance with applicable state law.
21. Any alleged liability of the Defendant is limited to the allowable percentage of alleged culpability found and should be further limited by virtue of the fault of other parties or entities (appearing and non-appearing, named and un-named) and in accordance with applicable state law.
22. The alleged injuries or damages may be attributable to several causes and, accordingly, should be apportioned among the various causes according to the respective contribution of each cause of the harm sustained, if any.
23. The claim should be diminished in whole or in part by any amount paid or fairly allocable to any party that has settled or may settle.
24. Any verdict or judgment must be reduced by those amounts that have or will, with reasonable certainty, replace or indemnify, in whole or in part, for any past or future claimed loss, including from any collateral sources such as insurance, disability, social security, worker's compensation, or employee benefit programs.
25. Any liability for non-economic loss is limited in accordance with the alleged relative culpability of all persons or entities contributing to the total liability for alleged non-economic loss, including named parties and others over whom personal jurisdiction could have been obtained with due diligence.

26. The claims are barred, in whole or in part, based on a balancing of risk and utility factors.
27. The alleged damages were not caused by any failure to warn.
28. No warranty, express or implied, was made.
29. Claims for breach of express or implied warranty are barred for lack of privity.
30. Claims for breach of warranty are barred for lack of reliance.
31. Punitive damages are barred because applicable procedures fail to provide specific limits or standards as to the amount of any such award.
32. Punitive damages are barred because applicable procedures do not provide sufficient notice of the type of conduct on which an award of punitive damages may be based.
33. Punitive damages are barred because applicable procedures fail to provide clear, consistent standards for appellate review of an award of punitive damages.
34. Punitive damages are barred because applicable procedures may allow for the consideration of inappropriate evidence, such as wealth, in assessing punitive damages.
35. An award of punitive damages as alleged would violate one or more of the protections provided by the United States Constitution and/or any other applicable state statute or constitution or law.
36. Defendant relies on all applicable defenses afforded it under the Tennessee Product Liability Act of 1978, Tenn. Code Ann. § 29-28-101, *et seq.*
37. Other defenses may be relied on, including any that may be asserted by others, or that may become available or apparent during proceedings in this case. The right to amend and incorporate such defenses hereby is reserved.

WHEREFORE, Defendant prays judgment of this Court

- a. Dismissing the Complaint against it, with prejudice;
- b. Awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. Granting such other relief, both legal and equitable, that the Court deems just and proper.

Respectfully submitted,

BAKER, DONELSON, BEARMAN, CALDWELL  
& BERKOWITZ, PC

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Date: February 11, 2013

*Attorneys for Medical Sales Management, Inc.*

**CERTIFICATE OF SERVICE**

I, Carrie W. McCutcheon, hereby certify that on this 11th day of February, 2013, the documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

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